

**Wednesday
August 17, 1988**

Part V

**Environmental
Protection Agency**

40 CFR Part 700

**Fees for Processing Premanufacture
Notices, Exemption Applications and
Notices, and Significant New Use
Notices; Final Rule**

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 700****[OPTS-260002A; FRL-3353-8]****Fees For Processing Premanufacture Notices, Exemption Applications And Notices, And Significant New Use Notices****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule.

SUMMARY: EPA is issuing a rule under section 26(b) of the Toxic Substances Control Act (TSCA). The rule requires manufacturers, importers, and processors to pay fees for premanufacture notices (PMNs), certain PMN exemption applications and notices, and significant new use notices submitted under TSCA section 5 (a) and (b) (section 5 notices). EPA is not requiring submitters to pay fees for low volume exemption notices under 40 CFR 723.50 and test market exemption applications under 40 CFR 720.38. EPA is requiring submitters to pay a fee of \$1,000 for PMNs for intermediate chemical substances when such PMNs are submitted simultaneously with a PMN for the "final product" related to the intermediate chemical substance. Submitters of all other section 5 notices, including the "final product" PMN, are required to pay a fee of \$2,500. However, EPA is only requiring a fee of \$100 for section 5 notices submitted by small business concerns.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern (daylight or standard as appropriate) time on August 31, 1988. This rule shall become effective on September 30, 1988.

FOR FURTHER INFORMATION CONTACT: Mike Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. EB-44, 401 M Street SW., Washington, DC 20460, (202-554-1404), TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This rule establishes fees for processing PMNs, certain exemption applications and notices, and significant new use notices. This rule also establishes certain remittance procedures.

Public reporting burden for this collection of information is estimated to average five minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and

reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

I. Authority

Section 26(b) of TSCA provides that the Administrator may, by rule, establish fees for persons required to submit data under sections 4 and 5 of TSCA (including premanufacture notices, significant new use notices, and exemption applications and notices) to defray the costs of administering TSCA. EPA must take into account a submitter's ability to pay the fee and the Agency's cost of reviewing the submitted data. Section 26(b) provides for maximum fees of \$100 for a "small business concern" and \$2,500 for all others. Section 26(b)(2) of TSCA gives EPA authority to define "small business concern."

In addition, since proposal of this rule, the Department of Housing and Urban Development—Independent Agencies Appropriations Act, 1988 (Pub. L. 100-202) was enacted which contains a provision authorizing EPA, in 1988, to assess and collect fees and to deposit an amount not to exceed \$25 million into a special fund which shall be available for appropriation, and remain available until expended, to carry out the Agency's activities in the programs for which the fees or charges are made.

II. Background

EPA issued a Notice of Availability of its "PMN User Fee Background Paper" (the paper), published in the *Federal Register* of July 11, 1986 (51 FR 25250) which included (1) the costs that the Agency believes may be defrayed by the collection of such fees, (2) the major options that the Agency had identified for implementing section 26(b), (3) a preliminary estimate of the economic impacts of such options, and (4) a possible definition of "small business concern."

On April 20, 1987, EPA issued a proposed rule (52 FR 12941) to establish a fee of \$100 for section 5 notices submitted by small business concerns, for low-volume exemption notices, and for test market exemption applications; and \$2,500 for all other section 5 notices.

The costs that EPA believes may be defrayed through fees collected pursuant to section 26(b) include all costs

associated with receiving, processing, storing, and analyzing data submitted pursuant to section 5, as well as all costs associated with regulatory and other actions that may be prompted by a submission. The direct cost elements that may be defrayed include the salaries and expenses (including supplies, training, travel, and equipment) of the EPA Office of Toxic Substances personnel associated with these section 5 activities, and the cost of associated data processing, computer equipment, and contractor effort. Direct costs also include support functions such as secretarial, clerical, and supervisory management. Indirect costs that may be defrayed include research and development in support of the PMN program. In addition, the Agency incurs other general overhead such as personnel processing, administrative management, budget execution, rent, and utilities.

EPA's analysis of direct costs (EPA, Office of Toxic Substances. D. Gutenson and J. Newsome. "Regulatory Impact Analysis") indicates that certain costs are generally incurred with every type of section 5 notice. These costs are associated with the activities of providing pre-filing assistance to submitters, providing protection for confidential business information (CBI), processing, duplicating, and storing documents contained in submission, and initial risk screening (usually including chemical characterization, environmental and human exposure analysis, and a preliminary toxicity review (including human and environmental effects)). These costs add up to approximately \$3,500 per submission. Office of Toxic Substances overhead, including supervisors and managers, clerical and secretaries, adds another \$1,800 per submission. Those submissions that require more detailed analysis and regulatory action cost approximately \$13,000 to \$15,000 more per submission. None of the above costs include indirect Agency costs, i.e., general Agency overhead such as costs incurred by the Office of General Counsel and the Office of Administration, and research and compliance costs.

The fees that the Agency is establishing pursuant to section 26(b) will recover substantially less than the total costs of administering section 5. For fiscal 1987, total Agency costs, both direct and indirect, could each approximately \$22 million compared to the maximum recovery of costs that the Agency could receive pursuant to section 26(b) of approximately \$3.8 million.

EPA received over 20 comments from the public on the proposed rule, and this final rule includes changes in response to the public comments. Those changes are discussed to Unit IV below.

III. Provisions of the Rule

After careful analysis of all the comments received by EPA of the proposed rule, and review of its economic analysis, the Agency has decided to establish a fee of \$100 for all section 5 notices received from small business concerns, \$1,000 for section 5 notices for certain intermediate chemical substances, and \$2,500 for all other section 5 submissions, except low-volume exemption notices and test market exemption applications for which no fee is required. The fees will be collected at the time of submission of the section 5 notice. EPA also has defined "small business concern" as any firm whose sales when combined with its parent company's (or the firm's sales, if no parent exists) totaled \$40 million or less in its fiscal year preceding the submission date of its section 5 notice.

The rule also clarifies the status of joint submitters. EPA allows persons to submit section 5 notices jointly with others (for example, see 40 CFR 720.40(e)). The fee is the same for a joint submission of a section 5 notice as for the same kind of notice submitted by a single firm. However, with respect to the lower \$100 fee for small business concerns, the lower fee does not apply to a joint submission unless all the joint submitters qualify as small business concerns under the proposed definition. Each of the joint submitters is required in the section 5 notice to certify that it qualifies as a small business concern under § 700.43.

IV. Response To Comments

The following unit summarizes the major comments and discusses the changes in the final rule in response to those comments.

EPA received a number of comments suggesting that the Agency's costs of administering the fee program might substantially offset its financial benefit. The Agency's economic analysis shows that the fee program should generate \$3.8 million; the costs of administering the program are estimated to total \$35,000. The Agency believes that the administrative costs are a negligible percent of the expected revenues.

Most comments asserted that the establishment of fees for section 5 notices could or would affect innovation, although all but three of these failed to comment on the degree of the effect. One industry association and one company asserted that the 10

percent foregone submission rate that EPA attributed to its proposed rule was sufficiently high to contravene TSCA section 2(b)(3) which directs the Agency to exercise its authority so as "not to impede unduly or create unnecessary economic barriers to technological innovation * * *". Another industry association, whose comments were subscribed to by a number of member companies, suggested that a correct analysis of the data upon which EPA relied for its economic analysis would indicate a foregone submission rate of about one-third, or over three times EPA's estimate.

With respect to the foregone submission rate of 10 percent associated with the proposed rule, and the 7.3 percent rate associated with the final rule, EPA believes that these estimates are very conservative and cannot be equated exactly with the fees' true effect on innovation. Unit V below clarifies this observation. The agency also believes that Congress clearly intended that it collect fees for section 5 notices and that inherent in that intention is the notion that fees will cause some firms to decide not to submit notices. However, the Agency believes that the rule's effect on innovation has been carefully weighed against the purpose of section 26(b), that is, to raise revenues to defray Agency costs, and thus is not "undue" as that term is used in section 2.

Concerning the foregone submission rate that should be calculated from the data base that the Agency used for its economic analysis (Centaur Associates Inc, 1985: Analysis of Withdrawn and Voluntarily Tested PMNs), the comment fails to take into account the Agency's statements with respect to the limits to the value of the Centaur study in predicting a company's decision to submit a PMN. The Centaur study was designed to evaluate a firm's attitudes to initiating testing after EPA had already issued a section 5(e) or 5(f) order placing restrictions on a new substance's production or use. The Agency is aware, from anecdotal evidence, that some firms' decisions not to test stemmed from liability concerns and considerations other than cost. The Agency's economic analysis also notes other misleading effects that would result from strictly interpreting the Centaur study. Consequently, the Agency used the Centaur study to estimate firms' marketing behavior from ranges of financial effects. Thus, as EPA stated in its January 1987 "Economic Analysis of Proposed PMN User Fee Rule" (in support of its April 20, 1987 proposed rule), " * * * if user fees are no more than 1.0 percent of the present value of sales, the user fees should have

a minimal impact on PMN sales and profits and mandatory user fees will not affect a firm's decision to commercialize the PMN chemical. User fees in the range of 1.0 to 3.0 percent of the expected present value of sales were assumed to have a moderate impact (i.e. 50 percent) on sales and an indeterminate effect on a firm's marketing decisions. If user fees are 3.0 percent or more of the present value of sales, it was assumed that user fees would have a severe impact on sales and that the impact is likely to prevent the firm from submitting a PMN."

EPA, in its reevaluation of the impact of its proposed fees on innovation, determined that low-volume exemption notices and test market exemption applications were extremely sensitive to even a nominal fee of \$100. The Agency's analysis shows a foregone submission rate of 36 percent for the low-volume exemption notices and 22 percent for the test market exemption applications. Because the Agency estimated fee revenue of less than \$20,000 for these two categories of submissions combined, and considering their apparent high sensitivity to even a nominal fee, EPA decided not to establish any fee for these two types of submissions.

A number of comments suggested that companies be permitted to pay either all or a portion of the appropriate fee at the time they submitted their Notice of Commencement of Manufacture or Import (NOC) to the Agency. As EPA stated in its April 20, 1987 proposed rule, its fee structure would not sufficiently defray the Agency's costs of reviewing PMNs (which is not dependent on new chemical substances' commercialization) if it permitted payment of fees with an NOC. The Agency estimates that it would receive less than \$1.5 million annually if it collected fees with NOCs. Furthermore, the Agency received no compelling arguments that collecting fees up front would have a significant impact on commercialization. One comment on the Agency's "PMN User Fee Background Paper" (see unit VI. RULEMAKING RECORD) stated that fees would not be a deciding factor as to commercialization after the PMN review is completed.

EPA received comments pointing out that the Agency treats consolidated PMNs as one in all respects except identification numbers, and consequently, it would be reasonable to charge just one fee for such consolidated PMNs. PMNs are consolidated as a result of a prenotice agreement between EPA and the submitter that the chemical

substances in question are nearly identical in structure and are expected to have the same properties. EPA establishes one file and reviews the consolidated PMNs in the identical manner as a single unconsolidated PMN. The Agency did not address this issue in its proposed rule (although it did consider the issue of PMNs related to a sequence of intermediates in the same manufacturing process). EPA agrees that because it treats a consolidated PMN as one notice for review purposes, it is reasonable to charge just one fee for a consolidated PMN and has modified the rule accordingly.

EPA, in response to a comment, is clarifying what it means by the term "sequenced intermediate". The Agency means a section 5 notice for any new chemical substance that is "intermediate" of another new chemical substance for which a section 5 notice is also submitted. 40 CFR 720.3 defines "intermediate" as any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of other chemical substances or mixtures, or that is intentionally present for the purpose of altering the rates of such chemical reactions.

In response to comments suggesting that charging a substantial fee for "intermediate" PMNs would create a significant hurdle to commercialization, EPA reevaluated the effect that a range of fees would have on the rate of foregone submissions for intermediate chemical substances. EPA's analysis shows that charging a fee of either \$1,000 or \$2,500 for each intermediate PMN that is submitted simultaneously with a "final product" PMN (for which a \$2,500 fee is also paid) would result in a foregone submission rate between 1 percent and 3 percent higher than the rate for all section 5 notices subject to the fee schedule in this rule. EPA has decided to impose the \$1,000 fee on the "intermediate" submissions primarily to promote the policy goals of more efficient administration and review, and to save the resources associated with multiple duplicative reviews when the "final product" PMN and the "intermediate" PMNs are submitted to EPA and reviewed at different times.

EPA asked for comments concerning the impact of charging the proposed \$2,500 fee for polymer exemption PMNs and received eight comments suggesting either a \$100 fee, reduced fee, or no fee. EPA reanalyzed the impact of a \$2,500 fee on polymer exemption PMNs and concluded that 11.1 percent of such submissions would be foregone. Because

that rate is not significantly different from either the overall foregone submission rate associated with the proposed rule (10 percent) or of the final rule (7.3 percent), and because the expected revenues involved (over \$500,000) are a significant proportion of the total revenues expected from the fee program, EPA decided to retain the \$2,500 fee for this category of submission.

EPA received two comments that express the concern that upcoming Agency rules for treating "new" microorganisms for PMN purposes may result in a fee burden that would have a chilling effect on innovation. The Agency had little experience with the subject of PMNs for microorganisms (EPA has received 12 PMNs to date for microorganisms). However, the Agency has, and expects to continue, to expend considerable resources reviewing this category of submission and has received no data or compelling argument to support lowering or eliminating fees for these submissions. The Agency will be considering fee issues when it proposes rules for review of microorganisms under TSCA. EPA recommends that companies comment on the effect of fees on the innovation of new microorganisms at the time that the Agency proposes those rules.

A number of comments questioned EPA's authority to collect fees pursuant to TSCA section 26 because at the time EPA proposed its fee rule the monies were expected to go to the general Treasury and thus not directly benefit the Agency. EPA's authority to collect fees under section 26(b) is not dependent on the disposition of the funds collected. In any event, as discussed in Unit I. above, recent budget legislation (Pub. L. 100-202) establishes a special fund for all agency user fees and provides for expenditure of those funds by the Agency subject to Congressional appropriation.

One comment recommended EPA established a \$100 fee for any section 5 notice that did not receive Agency review subsequent to its Chemistry Review and Search Strategy (CRSS) decision. The Agency has determined that it spends more than \$2,500 on handling a submission through the CRSS decision point, and is not persuaded that a lower fee is justified for this category of submission based solely on the argument that these submissions receive less attention than submissions that are reviewed subsequent to the CRSS decision.

In response to comments requesting that the Agency refund fees collected for

notices for chemical substances that, subsequent to payment, are found by the Agency to be already on the Inventory, EPA has modified the rule to provide for such refunds.

One comment suggested crediting fees against test expenses. While such crediting might promote some increase in worthwhile testing, the Agency believes that such effect is problematic; the crediting would be very difficult to administer and it probably would result in negligible fee revenues.

Concerns were expressed that EPA's review process will be unduly delayed as a result of a submitter's check going to a location different than the section 5 notice destination. EPA will review section 5 notices in the same manner that the Agency has been reviewing them provided that submitters certify on their submission that they have paid the appropriate fee. The Agency is establishing procedures to verify the receipt of the remittances that should provide adequate time to make the verification. Should EPA, subsequent to its verification effort, determine that the appropriate fee was not remitted at the time the section 5 notice was submitted, the Agency will consider the notice to be incomplete and will so notify the submitter. Note that submissions will be considered incomplete if they lack a certification that the fee has been paid.

EPA received a number of comments suggesting various changes to the Agency's interpretation of TSCA that, if adopted, would make many PMNs unnecessary, or would permit a greater number of PMN exemptions. The Agency is not addressing these comments because they are beyond the scope of this rulemaking.

A number of comments addressed the question of the international impact of the fees. One importer suggested that the fees would create a marketing advantage for companies already established in the U.S.; one domestic company suggested that because fees would adversely affect domestic innovation, domestic producers will increasingly find themselves at the mercy of innovative imports; one association and a number of domestic companies asserted that because importers likely would not pay fees for intermediate chemicals, then their "final product" chemicals would have a competitive advantage over the domestic producer who did pay fees for intermediate as well as "final product" chemicals. The Agency does not believe that the modest level of fees contained in this rule would significantly affect the competitiveness of domestic producers

vis-a-vis importers any more than it would affect innovation. The Agency's analysis of the effect of fees on decisions not to pursue PMN review suggests that fees in most instances will not affect a producer's decision to market and compete against either another domestic producer or an importer.

V. Economic Impacts

A. Introduction

In the Regulatory Impact Analysis (RIA), EPA considered the costs to society of this rule as being the sum of the direct costs to the government of administering the fee program and the net benefits that society would have realized from the new chemical substances that are foregone as a result of the fee rule. The fees themselves are not social costs, but rather transfers (the cost to industry of the fees equals the revenue received by the Agency). From the perspective of the regulated community, however, the fees are additional costs of doing business, and the RIA considers the impacts of these fees in relation to revenue from new chemical substances.

The Agency estimates that tracking and validating fees will cost the Agency approximately \$29,000 to \$35,000 per year. The Agency cannot quantitatively estimate the social cost of foregone activities, but it has estimated the number of foregone submissions, and has used this approach to reflect the potential for adverse effect on chemical innovation. EPA estimates that under the final rule 7.3 percent of the expected number of new chemical substance submissions would be foregone as a result of the user fee. The transfer (cost to industry and Agency revenue) is estimated to be \$3.8 million.

B. Methodology

To assess fully the costs of the fees to society, the Agency would need first to estimate the impact on the expected profitability of the new chemical substance as a result of any potential fee. Since the Agency believes that at some reduced level of profitability, a firm will choose not to submit a notice for a new chemical substance rather than incur any additional costs prior to commercialization, the second step would be to translate the impact on profitability into an estimate of the number of new substances that would be foregone. The third step would be to estimate the benefits associated with those foregone new substances. The Agency cannot estimate the benefits from the foregone new substances; the RIA captures the costs of the fee rule by

addressing the first two steps above, i.e., by analyzing the impact to industry in terms of the rate of foregone new substance submissions from any potential fee.

The impact is estimated by examining user fees as a portion of the present value of expected sales for a sample of new chemical substances, (potentially submitted in PMNs and exemptions). The Agency has observed a very low threshold for which companies decide to withdraw a submission rather than incur additional upfront costs. Decision criteria were developed from these observed thresholds which are used to predict the effect a user fee will have on a firm's decision to submit.

The Agency initially examined the impacts for 4 regulatory options. In addition to the categories of submissions considered in the economic analysis to support the proposed rule (small businesses, low volume exemptions and polymers), this analysis also estimates the impacts on submission of test market exemption applications and PMNs for intermediates (sequences of intermediates in the same manufacturing process).

The regulatory options are shown in Table I below.

TABLE I.—REGULATORY OPTIONS

Category description	Regulatory options			
	1	2	3	4
	(dollars per submission)			
Small business	100	100	100	100
Low volume exemption	100	100	100	100
Test market exemption	100	100	100	100
Polymer PMNs	2500	2500	100	100
Intermediate PMNs	2500	¹ 100 500 1000	2500	100
Others	2500	2500	2500	2500

¹ Regulatory Option 2 actually examines 3 alternative fees for PMNs for sequences of intermediates: \$100, \$500, \$1000. In each case, the fee for the final PMN in the sequence is set at \$2,500.

C. Impacts

The Agency estimates that 11.4 to 12.7 percent of submissions would be foregone as a result of the fees defined in these regulatory options. EPA estimates the cost of the fees (as well as agency revenue) to be between \$3.28 and \$3.99 million. Table II summarizes the impacts of options 1-4.

TABLE II.—IMPACTS OF INITIAL REGULATORY OPTIONS

Regulatory options	Percentage of submissions foregone	Total costs to industry (=EPA revenue) dollars million
1	12.7	3.99
2	12.2-12.5	3.87
3	11.9	3.49
4	11.4	3.28

The RIA indicates that two types of submissions are very sensitive to even low fees. Both low volume exemption notices (LVENs) and test market exemption applications (TMEAs) have high foregone submission rates (38 and 22.5 percent, respectively) at low (\$100) user fee requirements. Because of the extreme sensitivity of these two types of submissions to low fees, the Agency re-evaluated the impacts of each regulatory option with a \$0 fee LVENs and TMEAs. The results are shown in Table III below.

TABLE III.—IMPACTS OF MODIFIED REGULATORY OPTIONS

Regulatory option	Percentage of foregone submissions	Cost of submissions (=EPA revenue)
1 ¹	7.5	3.97
2 ¹	7.0-7.3	3.84
3 ¹	6.7	3.47
4 ¹	6.2	3.26

¹ Options are the same as options 1-4 in Table I, except that fees for low volume exemption notices and test market exemption applications are set at zero.

Providing an exemption to LVEN and TMEA submissions reduces the foregone submission rate approximately 50 percent for each regulatory option. The total cost to industry of the fee as well as the Agency revenue is reduced by less than 1.0 percent.

Under the final rule (modified regulatory option 2) the fee for submissions from small businesses is set at \$100, the fee for low volume exemption notices and test market exemption applications is set at zero, the fee for sequences of intermediates is set at \$1000 for each (with the fee for the final submission in the sequence set at \$2500), and the fee for all other submissions is set at \$2500. The Agency estimates that, with this fee structure, 7.3 percent of the expected number of new chemical substance submissions would be foregone as a result of the fees. This is probably an upper bound estimate of the impacts.

There are several sources of bias introduced that could result in an overestimate of the impacts. First, the

impact for the categories of submissions is based on a sample of submissions. The characteristics of some of the categories have changed since the time frame which the sample was drawn. Lower impacts would be expected if these differences could be quantitatively factored into the analysis.

Second, the decision criteria used to predict whether a firm will be choose to submit are based on the observed behavior of firms in response to a request for testing in a TSCA section 5(e) order. Thus, the firm was operating with the knowledge that the Agency had health or environmental concerns over the introduction of the new chemical substance. A given dollar amount of fee is not expected to have as great an impact on the firm's decision to submit a notice as would the same dollar amount of a testing requirement. Therefore, the decision criteria result in an overestimate of foregone submissions.

Finally, although 7.3 percent of submissions may be foregone, this does not necessarily mean that a similar percentage of the value of new chemical substance innovation will be lost. Indeed, it seems likely that the substances in those submissions which are foregone would be among the least valuable; therefore the loss to society would be significantly smaller than the seven percent estimate would imply.

VI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS-260002A). A public version of the record, without any confidential business information, is available to the public in the TSCA Public Docket Office, Rm. NE-G004, 401 M Street SW., Washington, DC 20460, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The record includes information considered by EPA in developing this rule. The record now includes the following categories of information:

1. Federal Register notices.
2. Support documents.
3. Public comments.

VII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore subject to the requirement of Regulatory Impact Analysis. This rule is not major as that term is defined in section 1(b) because: The annual effect on the rule on the economy will be less than \$100 million (less than \$4 million); it will not cause any significant increase in costs or prices for any sector of the economy or for any geographic region;

and it will not result in any significant adverse effects on competition, employment, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets.

This rule was submitted to the Office of Management and Budget (OMB) for review prior to publication as required by Executive Order 12291.

B. Regulatory Flexibility Act

As required by the Regulatory Flexibility Act (5 U.S.C. (b)), EPA certifies that this rule will not have a significant economic impact on a substantial number of small businesses because the fee proposed for small business concerns, although it will adversely affect the submission of some notices for new chemical substances is unlikely to have a significant impact on any firm's overall profitability.

C. Paperwork Reduction Act

The information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* have been assigned OMB control number 2070-0012 and 2070-0038.

The public reporting burden for this collection of information is estimated to average five minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

1. Chief, Information Policy Branch (PM-223), EPA, 401 M Street SW., Washington, DC 20460
2. Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20503

(Attn: Desk Officer for EPA)

List of Subjects in 40 CFR Part 700

Chemicals, Environmental protection, User fees.

Dated: August 9, 1988.

Lee M. Thomas,
Administrator.

Therefore, 40 CFR, Chapter I, Subchapter R, is amended by adding Part 700, consisting at this time of Subpart C, to read as follows:

PART 700—GENERAL

Subparts A and B—[Reserved]

Subpart C—Fees

Sec.

- 700.40 Purpose and applicability.
- 700.43 Definitions.
- 700.45 Fee payments.
- 700.49 Failure to remit fees.

Authority: 15 U.S.C. 2625.

§ 700.40 Purpose and applicability.

(a) *Purpose.* The purpose of this subpart is to collect fees from manufacturers, importers, and processors who submit notices and applications to EPA under section 5 of the Toxic Substances Control Act (15 U.S.C. 2604) to defray part of EPA's cost of administering the Act.

(b) *Applicability.* This subpart applies to all manufacturers, importers, and processors who submit certain notices and applications to EPA under section 5 of the Act.

§ 700.43 Definitions.

Definitions in section 3 of the Act (15 U.S.C. 2602), as well as definitions contained in §§ 704.3 and 720.3 of this chapter, apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

"Consolidated premanufacture notice" or "consolidated PMN" means any PMN submitted to EPA that covers more than one chemical substance (each being assigned a separate PMN number by EPA) as a result of a prenotice agreement with EPA (*See* 48 FR 21734).

"Exemption application" means any application submitted to EPA under section 5(h)(2) of the Act.

"Exemption notice" means any notice submitted to EPA under § 723.175 of this chapter.

"Final product" means a new chemical substance (as "new chemical substance" is defined in § 720.3 of this chapter) that is manufactured by a person for distribution in commerce, or for use by the person other than as an intermediate.

"Intermediate premanufacture notice" or "intermediate PMN" means any PMN submitted to EPA for a chemical substance which is an intermediate (as "intermediate" is defined in § 720.3 of this chapter) in the production of a final product, provided that the PMN for the intermediate is submitted to EPA at the same time as, and together with, the PMN for the final product and that the PMN for the intermediate identifies the final product and describes the chemical reactions leading from the intermediate to the final product. If PMNs are submitted to EPA at the same time for

several intermediates used in the production of a final product, each of those is an intermediate PMN if they all identify the final product and every other associated intermediate PMN and are submitted to EPA at the same time as, and together with, the FMN for the final product.

"Joint submitters" means two or more persons who submit a section 5 notice together.

"Person" means a manufacturer, importer, or processor.

"Premanufacture notice" or "PMN" means any notice submitted to EPA pursuant to section 5(a)(1)(A) of the Act in accordance with Part 720 of this chapter or § 723.250 of this chapter.

"Section 5 notice" means any PMN, consolidated PMN, intermediate PMN, significant new use notice, exemption notice, or exemption application.

"Significant new use notice" means any notice submitted to EPA pursuant to section 5(a)(1)(B) of the Act in accordance with Part 721 of this chapter.

"Small business concern" means any person whose total annual sales in the person's fiscal year preceding the date of the submission of the applicable section 5 notice, when combined with those of the parent company (if any), are less than \$40 million.

§ 700.45 Fee payments.

(a) *Persons who must pay fees.* Persons submitting a section 5 notice to EPA shall remit for each such notice the appropriate fee identified in paragraph (b) of this section in accordance with the procedures in paragraph (e) of this section.

(b) *Fees.* Persons shall remit fee payments to EPA as follows:

(1) *Small business concerns.* Small business concerns shall remit a fee of \$100 for each section 5 notice submitted.

(2) *Others.* Persons other than small business concerns shall remit fees according to the type of section 5 notice as follows:

(i) *Premanufacture notices and consolidated premanufacture notices.* Persons shall remit a fee of \$2,500 for each PMN or consolidated PMN submitted.

(ii) *Intermediate premanufacture notices.* Persons shall remit a fee of \$1,000 for each intermediate PMN. However, for the PMN for the final product the person shall submit the fee in paragraph (b)(2)(i) of this section.

(iii) *Significant new use notices.* Persons shall remit a fee of \$2,500 for each significant new use notice submitted.

(iv) *Exemption applications.* Persons shall remit a fee of \$2,500 for each

exemption application submitted under section 5(h)(2) of the Act.

(v) *Exemption notices.* Persons shall remit a fee of \$2,500 for each exemption notice submitted under § 723.175 of this chapter.

(c) *No fee required.* Persons are exempt from remitting any fee for submissions under §§ 720.38 and 723.50 of this chapter.

(d) *Joint submitters.* Joint submitters of a section 5 notice are required to remit the appropriate fee identified in paragraph (b) of this section for each section 5 notice regardless of the number of joint submitters for that notice. To qualify for the fee identified in paragraph (b)(1) of this section, each joint submitter of a section 5 notice must qualify as a small business concern under § 700.43.

(e) *Remittance procedure.* (1) Each remittance under this section shall be in United States currency and shall be paid by money order, bank draft, or certified check drawn to the order of the Environmental Protection Agency.

(2) Each remittance shall be sent to the Environmental Protection Agency, HQ Accounting Operations Board, attention: TS/PMN, P.O. 360227M, Pittsburgh, PA 15251. The remittance shall not be sent to EPA with the section 5 notice. The section 5 notice is to be sent to Document Processing Center, Office of Toxic Substances (TS-790), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(3) Persons who submit a section 5 notice shall place a unique identifying number, which must include the letters "TS" followed by a combination of 8 numbers (letters may be substituted for some numbers), on the front page of each section 5 notice submitted. The same identifying number and the submitter's name must appear on the corresponding fee remittance under this section. If a remittance applies to more than one section 5 notice, the person shall include the name of the submitter, the identifying number for each section 5 notice to which the remittance applies, and the amount of the remittance which applies to each notice. Any remittance not having the identifying name and number described above will be returned to the remitter.

(4)(i) Each person who remits the fee identified in paragraph (b)(1) of this section for a PMN, consolidated PMN, intermediate PMN, or significant new use notice shall write or type the words, "The company named in Part 1, section A is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b)." under "CERTIFICATION" on

Page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25 (4-26-83)).

(ii) Each person who remits the fee identified in paragraph (b)(1) of this section for an exemption application under section 5(h)(2) of the Act shall include the words, "Each company identified in this application is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b)." in the exemption application.

(iii) Each person who remits the fee identified in paragraph (b)(1) of this section for an exemption notice under § 723.175 of this Chapter shall include the words, "Each company identified in this notice is a small business concern under 40 CFR 700.43 and has remitted a fee of \$100 in accordance with 40 CFR 700.45(b)." in the certification required in § 723.175(i)(1)(x) of this chapter.

(5)(i) Each person who remits a fee identified in paragraph (b)(2) of this section for a PMN, consolidated PMN, intermediate PMN, or significant new use notice shall write or type the words, "The company named in Part 1, section A has remitted the fee specified in 40 CFR 700.45 (b)." under "CERTIFICATION" on page 2 of the Premanufacture Notice for New Chemical Substances (EPA Form 7710-25 (4-26-83)).

(ii) Each person who remits the fee identified in paragraph (b)(2) of this section for an exemption application under section 5(h)(2) of the Act shall include the words, "Each company identified in this application has remitted a fee of \$2,500 in accordance with 40 CFR 700.45(b)." in the exemption application.

(iii) Each person who remits the fee identified in paragraph (b)(2) of this section for an exemption notice under § 723.175 of this chapter shall include the words, "Each company identified in this notice has remitted a fee of \$2,500 in accordance with 40 CFR 700.45(b)." in the certification required in § 723.175(i)(1)(x) of this chapter.

(f) *Fee refunds.* EPA will refund any fee paid for a section 5 notice whenever the Agency determines:

(1) That the chemical substance that is the subject of a PMN, intermediate PMN, exemption application, or exemption notice is not a new chemical substance as of the date of submission of the notice.

(2) In the case of a significant new use notice, that the notice was not required.

(3) The notice is incomplete under § 720.65(c) of this chapter.

(Approved by the Office of Management and Budget under Control Number 2070-0012 and 2070-0038)

§ 700.49 Failure to remit fees.

EPA will not consider a section 5 notice to be complete unless the appropriate certification under § 700.45(e) is included and until the appropriate remittance under § 700.45(b) has been sent to EPA as provided in § 700.45(e) and received by EPA. EPA will notify the submitter that the section 5 notice is incomplete in accordance with § 720.65(c) of this Chapter.

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